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Substitute Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheep

of 6

Complete If Known

Application Number	10/782,871
Filing Date	February 23, 2004
First Named Inventor	Malcolm King
Art Unit	1617
Examiner Name	
Attorney Docket Number	11157-74

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

**Examiner
Signature**

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Date Considered

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<i>(Use as many sheets as necessary)</i>				<i>Filing Date</i>	February 23, 2004
				<i>First Named Inventor</i>	Malcolm King
				<i>Art Unit</i>	1617
				<i>Examiner Name</i>	
Sheet	2	of	6	<i>Attorney Docket Number</i>	11157-74

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
UR	1	KING, M., AND B.K. RUBIN. 1996. Mucus physiology and pathophysiology: Therapeutic aspects. Chapter 13 of: Derenne, J.P., W.A. Whitelaw, and T. Similowski, eds. Acute Respiratory Failure in COPD (Lung Biology in Health and Disease Series) Marcel Dekker, New York, 391-411.	T ²	
	2	RUBIN, B.K., R.P. TOMKIEWICZ, AND M. KING. 1997. Mucoactive agents: Old and new. Chapter 7 of: Wilmott, R.W., ed. The Pediatric Lung. Birkhäuser, Basel, 155-178.	T ²	
	3	SHEFFNER, A.L. 1963. The reduction in vitro in viscosity of mucoprotein solutions by a new mucolytic agent, N-acetylcysteine. Ann. N. Y. Acad. Sci. 106:298-310.	T ²	
	4	DASGUPTA, B., AND M. KING. 1996. Reduction in viscoelasticity of cystic fibrosis sputum in vitro with combined treatment by Nacystelyn and rhDNase. Pediatr. Pulmonol. 22:161-166.	T ²	
	5	APP, E.M., R. KIESELMANN, D. REINHARDT, H. LINDEMANN, B. DASGUPTA, M. KING, AND P. BRAND. 1998. Sputum rheology changes in cystic fibrosis lung disease following two different types of physiotherapy: Flutter vs. autogenic drainage. Chest 114:171-177.	T ²	
	6	FENG, W., H. GARRETT, D.P. SPEERT, AND M. KING. 1998. Improved clearability of cystic fibrosis sputum with dextran treatment in vitro. Am. J. Respir. Crit. Care Med. 157:710-714.	T ²	
	7	WILLS, P.J., R.L. HALL, W.M. CHAN, AND P.J. COLE. 1997. Sodium chloride increases the ciliary transportability of cystic fibrosis and bronchiectasis sputum on the mucus-depleted bovine trachea. J. Clin. Invest. 99:9-13.	T ²	
	8	KING, M., B. DASGUPTA, R.P. TOMKIEWICZ, AND N.E. BROWN. 1997. Rheology of cystic fibrosis sputum after in vitro treatment with hypertonic saline alone and in combination with rhDNase. Am. J. Respir. Crit. Care Med. 156:173-177.	T ²	
	9	SHAK, S., D.J. CAPON, R. HELLMISS, S.A. MARSTERS, AND C.L. BAKER. 1990. Recombinant human DNase I reduces the viscosity of cystic fibrosis sputum. Proc. Natl. Acad. Sci. U.S.A. 87:9188- 9192.	T ²	
	10	VASCONCELLOS, C.A., P.G. ALLEN, M. WOHL, J.M. DRAZEN, AND P.A. JANMEY. 1994. Reduction in viscosity of cystic fibrosis sputum in vitro by gelsolin. Science 263:969-971.	T ²	
✓	11	DAVISKAS, E., S.D. ANDERSON, J.D. BRANNAN, H.K. CHAN, S. EBERL, AND G. BAUTOVICH. 1997. Inhalation of dry-powder mannitol increases mucociliary clearance. Eur. Respir. J. 10:2449-2454.	T ²	

Examiner Signature	<i>Chet Faler</i>	Date Considered	<i>Feb 10/2007</i>
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/782,871
(Use as many sheets as necessary)				Filing Date	February 23, 2004
				First Named Inventor	Malcolm King
				Art Unit	1617
				Examiner Name	
Sheet	3	of	6	Attorney Docket Number	11157-74

NON PATENT LITERATURE DOCUMENTS				
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UR	12	SHIBUYA, Y., P.J. WILLS, S. KITAMURA, AND P.J. COLE. 1997. The effect of lactose on mucociliary transportability and rheology of cystic fibrosis and bronchiectasis sputum. <i>Eur. Respir. J.</i> 10:321s.		T ²
	13	FUCHS, H.J., D.S. BOROWITZ, D.H. CHRISTIANSEN, E.M. MORRIS, M.L. NASH, B.W. RAMSEY, B.J. ROSENSTEIN, A.L. SMITH, AND M.E. WOHL. 1994. Effect of aerosolized recombinant human DNase on exacerbations of respiratory symptoms and on pulmonary function in cystic fibrosis. <i>N. Engl. J. Med.</i> 33:637-648.		
	14	RANASINHA, C., B. ASSOUIFI, S. SHAK, D. CHRISTIANSEN, H. FUCHS, D. EMPEY, D. GEDDES, AND M. HODSON. 1993. Efficacy and safety of short-term administration of aerosolized recombinant human DNase I in adults with stable stage cystic fibrosis. <i>Lancet</i> 342: 199-202.		
	15	KING, M., AND B.K. RUBIN. 1999. Mucus controlling agents: Past and present. In: Rau, J.L., ed. <i>Aerosolized Drugs for the Respiratory Tract</i> . <i>Respir Care Clinics N Amer.</i> in press.		
	16	FENG, W., S. NAKAMURA, E. SUDO, M.M. LEE, A. SHAO, AND M. KING. 1999. Effects of dextran on tracheal mucociliary velocity in dogs in vivo. <i>Pulm. Pharmacol. Ther.</i> 12:35-41.		
	17	LEE, M.M., AND M. KING. 1998. Effect of low molecular weight heparin on the elasticity of dog mucus. <i>Clin. Invest. Med.</i> 21:S 102.		
	18	LEE M.M, H. GARRETT, E. SUDO, W.A. BOYD, AND M. KING. 1998. Mucociliary clearance increase due to low molecular weight heparin. <i>Pediatr. Pulmonol.</i> 38:S 17.		
	19	APP, E.M., J.G. ZAYAS, AND M. KING. 1993. Rheology of mucus and transepithelial potential difference: Small airways vs. trachea. <i>Eur. Respir. J.</i> 6: 67-75.		
	20	KING, M., S. KELLY, AND M. COSIO. 1985. Alteration of airway reactivity by mucus. <i>Respiration Physiol.</i> 62:47-59.		
	21	KING, M. 1988. Magnetic microrheometer. In: Braga, P.C., and L. Allegra, eds. <i>Methods in Bronchial Mucology</i> . Raven Press, New York, 73-83.		
WV	22	KING, M. 1987. The role of mucus viscoelasticity in cough clearance. <i>Biorheology</i> 24: 589-597.		

Examiner Signature	<i>Chad Faberwal</i>	Date Considered	Feb 15/2007
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(Use as many sheets as necessary)				Filing Date	February 23, 2004
				First Named Inventor	Malcolm King
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Sheet	4	of	6	Attorney Docket Number	11157-74

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UR	23	RUBIN, B.K., O. RAMIREZ, J.G. ZAYAS, B. FINEGAN, AND M. KING. 1990. Collection and analysis of respiratory mucus from individuals without lung disease. Am. Rev. Respir. Dis. 141:1040-1043.		T ²
	24	DAVISKAS, E., S.D. ANDERSON, I. GONDA, S. EBERL, S. MEIKLE, J.P. SEALE, AND G. BAUTOVICH. 1996. Inhalation of hypertonic saline aerosol enhances mucociliary clearance in asthmatic and healthy subjects. Eur. Respir. J. 9:725-732.		
	25	ROBINSON, M., A. HEMMING, J.A. REGNIS, D.L. BAILEY, M. KING, W. FENG, G.J. BAUTOVICH, AND P.T.P. BYE. 1998. Improved mucociliary clearance following nebulisation with hypertonic saline in adults with cystic fibrosis. In: Baum, G., ed. <i>Cilia, Mucus and Mucociliary Interactions</i> . Marcel Dekker, New York, 265-280.		
	26	TOMKIEWICZ, R.P., W.A. BOYD, W. FENG, E.M. APP, B.K. RUBIN, AND M. KING. 1997. Tracheal clearance and mucus rheology in healthy dogs after aerosolization of 3% and 7% hypertonic saline. Am. J. Respir. Crit. Care Med. 155:A780.		
	27	NAKAMURA S, SUDO E, W. FENG, M.M. LEE, W.A. BOYD, AND M. KING. 1998. Effects of hypertonic saline aerosolization on tracheal mucus clearance and mucus rheology in healthy dogs. Eur. Respir. J. 12(S28): 180s.		
	28	WINTERS, S.L., AND D.B. YEATES. 1997. Role of hydration, sodium, and chloride in regulation of canine mucociliary transport system. J. Appl. Physiol. 83:1360-1369.		
	29	TOMKIEWICZ, R.P., E.M. APP, G.T. DE SANCTIS, M. COFFINER, P. MAES, B.K. RUBIN, AND M. KING. 1995. A comparison of a new mucolytic N-acetylcysteine L-lysinate with N-acetylcysteine: Airway epithelial function and mucus changes in dog. Pulm. Pharmacol. 8:259-265.		
	30	SUDO, E., M.M. LEE, W.A. BOYD, AND M. KING. 1998. Effect of methacholine and uridine-5' triphosphate on tracheal mucus rheology in mice. Pediatr. Pulmonol. S 17:229.		
	31	TAI, S., H. KAI, T. KIDO, Y. ISOHAMA, K. TAKAHAMA, AND T. MIYATA. 1997. Effect of human neutrophil elastase on tracheal mucociliary transport in anesthetized quails. Jpn. J. Pharmacol. 75:439-442.		
	32	KING, M., A. GHAHARY, R. FRANKLIN, M. HIRJI, D. MALCHENKO, W.A. BOYD, H. GARRETT, AND M.M. LEE. 1999. Studies on aerosolized low mol. wt. heparin as a mucokinetic agent in dogs. Am. J. Respir. Crit. Care Med. 159:A474.		
↓	33	BJORCK, S., E. JENNISCHE, A. DAHLSTROM, AND H. AHLMAN. 1997. Influence of topical rectal application of drugs on dextran sulfate-induced colitis in rats. Dig. Dis. Sci. 42:824-832.		

Examiner Signature	<i>Chief Clerk</i>	Date Considered	Feb 5/2007
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UR	34	LORENTSEN, K.J., C.W. HENDRIX, J.M. COLLINS, D.M. KORNHAUSER, B.G. PETTY, R.W. KLECKER, C. FLEXNER, R.H. ECKEL, AND P.S. LIETMAN. 1989. Dextran sulfate is poorly absorbed after oral administration. Ann. Int. Med. 111: 561-568.		T ²
	35	BELLER, F.K., ZIMMERMAN, R.E., AND H. NIENHAUS. 1986 Biochemical identification of the mucus of pseudomyxoma peritonei as the basis for mucolytic treatment. Am. J. Obstet. Gynecol. 155:970-3.		
	36	RAO N. V. et al.; "Sulfated Polysaccharides Prevent Human Leukocyte Elastase-Induced Acute Lung Injury and Emphysema in Hamsters", American Review of Respiratory Disease, vol. 142, no. 2, 1990, pp. 407-412.		
	37	MOTOJIMA S. et al: "Effects of Anionic Polyelectrolyte Substance on Damages to Respiratory Epithelium Induced by Eosinophil Peroxidase", Dekkyo Journal of Medical Sciences, MIBU, JP, vol. 21, no. 2, 1994, pp. 123-134		
	38	FATH M. A. et al.: "Interaction of Secretory Leukocyte Protease Inhibitor with Heparin Inhibits Protease Involved in Asthma", Journal of Biological Chemistry, American Society of Biological Chemists, Baltimore, MD, US, vol. 273, no. 22, May 29, 1998, pp. 13563-13569.		
	39	COYLE A. J. et al.: "Role of Cationic Proteins in the Airway Hyperresponsiveness due to Airway Inflammation", American Journal of Respiratory and Critical Care Medicine, American Lung Association, New York, NY, US, vol. 150, no. 5, part 2, Nov. 1994, pp. S63-71.		
	40	BARGHOUTI SAMEER et al.: "Inhibition by Dextran of Pseudomonas Aeruginosa Adherence to Epithelial Cells", American Journal of Respiratory and Critical Care Medicine", vol. 154, no. 8, part 1, 1996, pp. 1788-1793.		
	41	COYLE ANTHONY J. et al.: "Cationic Proteins Induce Airway Hyperresponsiveness Dependent on Charge Interactions", American Review of Respiratory Disease, vol. 147, no. 4, 1993, pp. 898-900.		
	42	BARROWCLIFFE, MICHAEL P. et al.: "Pulmonary Clearance of Radiotracers After Positive End-Expiratory Pressure or Acute Lung Injury", J. Appl. Physiol. (1989), 66(1), 288-94.		
	43	BARROWCLIFFE M. P. et al.: "Clearance of Charged and Uncharged Dextrans from Normal and Injured Lungs", Journal of Applied Physiology, vol. 68, no. 1, 1990, pp. 341-347.		
✓	44	ATHAMNA ABED et al. "Adherence of Mycoplasma Pneumoniae to Human Alveolar Macrophages", Fems Immunology and Medical Microbiology, vol. 15, no. 2-3, 1996, pp. 135-141.		

Examiner Signature	<i>Chet Patel</i>	Date Considered	2/5/2007
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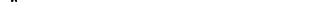
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